



REMARKS

In the Office Action¹, the Examiner rejected claims 1, 6, 7, 14, 20, and 21 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,937,883 to Prince ("*Prince*") in view of U.S. Patent No. 5,355,887 to lizuka et al. ("*lizuka*"); rejected claims 2 and 3 under 35 U.S.C. § 103(a) as being unpatentable over *Prince*, in view of *lizuka*, and further in view of U.S. Patent No. 5,363,844 to Riederer et al. ("*Riederer*"); rejected claim 9 under 35 U.S.C. § 103(a) as being unpatentable over *Prince*, in view of *lizuka*, in view of *Riederer*, and further in view of U.S. Patent No. 4,431,007 to Amazeen et al. ("*Amazeen*"); rejected claim 10 under 35 U.S.C. § 103(a) as being unpatentable over *Prince*, in view of *lizuka*, and further in view of U.S. Patent No. 6,314,312 to Wessels et al. ("*Wessels*"); rejected claims 11, 12, and 17-19 under 35 U.S.C. § 103(a) as being unpatentable over *Prince*, in view of *lizuka*, and further in view of EP 0940158 A1 to Hernandez-Guerra et al. ("*Hernandez-Guerra*"); and rejected claims 1, 12, and 13 under 35 U.S.C. § 103(a) as being unpatentable over *Hernandez-Guerra*, in view of *Prince*, and further in view of *lizuka*.

I. Regarding the rejections of claims 1, 6, 7, 14, 20, and 21 under 35 U.S.C. § 103(a) as being unpatentable over *Prince* in view of *lizuka*

Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 1, 6, 7, 14, 20, and 21 under 35 U.S.C. § 103(a) because a *prima facie* case of obviousness has not been established with respect to this claim.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the

¹ The Office Action contains a number of statements reflecting characterizations of the related art and the claims. Regardless of whether any such statement is identified herein, Applicant declines to automatically subscribe to any statement or characterization in the Office Action.

references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). M.P.E.P. § 2142, 8th Ed., Rev. 2 (May 2004), p. 2100-128.

A *prima facie* case of obviousness has not been established because, among other things, neither *Prince* nor *Iizuka*, taken alone or in combination, teach or suggest each and every element recited by claims 1, 6, 7, 14, 20, and 21.

Claim 1 recites a method including:

detecting the position of the patient's diaphragm by means of an array of at least two ultrasound transducer elements on the patient extending in the direction of the longitudinal (z) axis of the patient over the lung sinus, wherein the position of the diaphragm is determined based upon the difference between the signals received by the individual transducer elements.

(emphasis added). *Prince* discloses a system control 122 that "receives a gating signal from an ultrasonic detector system 129" (col. 4, lines 50-51). "[D]etector system 129 receives an electrical signal from an ultrasonic transducer 11 that is positioned to sense motion in the patient" (col. 4, lines 52-54).

The Examiner cites col. 10, lines 50-67 of *Prince* as allegedly constituting the claimed "at least two ultrasound transducer elements on the patient extending in the direction of the longitudinal (z) axis of the patient over the lung sinus, wherein the position of the diaphragm is determined based upon the difference between the signals received by the individual transducer elements" (Final Office Action at page 2). This is not correct.

This passage of *Prince* discloses producing gate signals indicative of patient respiration “by locating the Doppler range gate across the diaphragm by aiming the ultrasound beam through the liver in a longitudinal orientation” (col. 10, lines 60-63). When the diaphragm moves, a signal is produced and “can be used to follow respiratory rate and rhythm” (col. 10, lines 66-67). Nothing in this passage or any other passage of *Prince* teaches or suggests the claimed “at least two ultrasound transducer elements on the patient extending in the direction of the longitudinal (z) axis of the patient over the lung sinus, wherein the position of the diaphragm is determined based upon the difference between the signals received by the individual transducer elements,” as recited in claim 1.

lizuka fails to cure the deficiencies of *Prince*. *lizuka* discloses “an ultrasonic diagnostic apparatus capable of . . . displaying the hardness of tissues of human body organs” (col. 2, lines 52-54). There is no teaching in *lizuka* of “at least two ultrasound transducer elements on the patient extending in the direction of the longitudinal (z) axis of the patient over the lung sinus, wherein the position of the diaphragm is determined based upon the difference between the signals received by the individual transducer elements,” as recited in claim 1.

Accordingly, *Prince* and *lizuka* fail to establish a *prima facie* case of obviousness with respect to claim 1, for at least the reason that the references, even in combination, fail to teach each and every element of the claim. The rejection under 35 U.S.C. §103 is therefore improper. Claims 6 and 14 depend from claim 1 and are thus also allowable over *Prince* in view of *lizuka*, for at least the same reasons as claim 1.

Independent claim 7, though of different scope from claim 1, recites limitations similar to those set forth above with respect to claim 1. Claim 7 is therefore allowable for at least the reasons presented above. Claims 20 and 21 depend from claim 7 and are thus also allowable over *Prince* in view of *lizuka*, for at least the same reasons as claim 7.

II. Regarding the rejections of claims 2 and 3 under 35 U.S.C. § 103(a) as being unpatentable over *Prince*, in view of *lizuka*, and further in view of *Riederer*

Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 2 and 3 under 35 U.S.C. § 103(a) because a *prima facie* case of obviousness has not been established with respect to this claim. A *prima facie* case of obviousness has not been established because, among other things, neither *Prince*, *lizuka*, nor *Riederer*, taken alone or in combination, teach or suggest each and every element recited by claims 2 and 3.

Claims 2 and 3 depend from claim 1 and therefore include all of the elements recited therein. The Examiner states that “Riederer also teaches a calibration-breath-holding technique where the patient first assists in determining a diaphragm-stationary reference point . . .” (Office Action at page 3). Even assuming that this assertion is correct, which Applicant does not concede, *Riederer* fails to cure the deficiencies of *Prince* and *lizuka*.

Riederer discloses “a breath-hold monitor which visually feeds back to the patient diaphragmatic position” (col. 2, lines 3-5). “[T]he invention includes a respiratory monitor which measures the patient’s diaphragm position, a display which indicates diaphragm position to the patient during the scan, and means for triggering MRI data

acquisition when a reference diaphragm position is maintained for a preset time forward" (col. 2, lines 7-13).

Riederer does not disclose ultrasound transducer elements to detect a diaphragm position. Moreover, *Riederer* does not disclose using "the difference between the signals received by the individual transducer elements" to determine the position of the diaphragm. Therefore, *Riederer* does not teach or suggest "detecting the position of the patient's diaphragm by means of an array of at least two ultrasound transducer elements on the patient extending in the direction of the longitudinal (z) axis of the patient over the lung sinus, wherein the position of the diaphragm is determined based upon the difference between the signals received by the individual transducer elements," as recited in claim 1 and required by dependent claims 2 and 3.

At least because *Prince*, *Iizuka*, and *Riederer* fail to teach or suggest each and every element recited in independent claim 1 and required by dependent claims 2 and 3, no *prima facie* case of obviousness has been established with respect to claims 2 and 3. The rejection of claims 2 and 3 under 35 U.S.C. § 103(a) based on *Prince*, *Iizuka*, and *Riederer* is therefore improper.

III. Regarding the rejection of claim 9 under 35 U.S.C. § 103(a) as being unpatentable over *Prince*, in view of *Iizuka*, in view of *Riederer*, and further in view of *Amazeen*

Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claim 9 because a *prima facie* case of obviousness has not been established with respect to the claim.

Claim 9 depends from claim 7 and therefore includes all of the elements recited therein. The Examiner admits that *Prince*, *Iizuka*, and *Riederer* do not teach

"impedance change in the Z-direction with respect to diaphragm movement" (Office Action at page 3). However, the Examiner relies on *Amazeen* for allegedly teaching this claimed element (Office Action at pages 3-4).

Even assuming this allegation is true, which Applicant does not concede, *Amazeen* fails to cure the deficiencies of *Prince*, *Iizuka*, and *Riederer* discussed above. *Amazeen* discloses "an ultra-sound examination system which enables a real-time image, corresponding with the present location of a linear array or sector scan transducer to be displayed, and which when the transducer is moved in either direction, continues to display static images of anatomy contiguous with a real-time image all on the same display device" (col. 2, lines 28-35).

Amazeen does not teach or suggest "detecting the position of the patient's diaphragm by means of an array of at least two ultrasound transducer elements on the patient extending in the direction of the longitudinal (z) axis of the patient over the lung sinus, wherein the position of the diaphragm is determined based upon the difference between the signals received by the individual transducer elements," as recited in claim 7 and required by dependent claim 9.

At least because *Prince*, *Iizuka*, *Riederer* and *Amazeen* fail to teach or suggest each and every element recited in independent claim 7 and required by dependent claim 9, no *prima facie* case of obviousness has been established with respect to claim 9. The rejection of claim 9 under 35 U.S.C. § 103(a) based on *Prince*, *Iizuka*, *Riederer* and *Amazeen* is therefore improper.

IV. Regarding the rejection of claim 10 under 35 U.S.C. § 103(a) as being unpatentable over *Prince*, in view of *Iizuka*, and further in view of *Wessels*

Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claim 10 because a *prima facie* case of obviousness has not been established with respect to claim 10.

Claim 10 depends from claim 1 and therefore includes all of the elements recited therein. The Examiner asserts that “it would have been obvious in view of *Wessels* et al. . . . to track organ motion in association with biopsy in order that a small lesion such as P within the liver may be accurately targeted using the ultrasound as part of the tracking where ultrasound is used such as in *Prince*” (Office Action at pages 4). However, the Examiner’s unsupported assertions do not alter the fact that *Wessels* fails to cure the deficiencies of *Prince* and *Iizuka* discussed above.

Wessels discloses “a method and a system that enable an adequately precise acquisition of the movement of an organ or body region, so that a therapist or operator is provided with exact knowledge with respect to the position of the organ or therapy region of interest” (col. 1, lines 46-50). However, *Wessels* does not teach or suggest “detecting the position of the patient’s diaphragm by means of an array of at least two ultrasound transducer elements on the patient extending in the direction of the longitudinal (z) axis of the patient over the lung sinus, wherein the position of the diaphragm is determined based upon the difference between the signals received by the individual transducer elements”, as recited in claim 1 and required by dependent claim 10.

At least because *Prince*, *lizuka*, and *Wessels*, taken alone or in any reasonable combination, fail to teach or suggest each and every element recited in independent claim 1 and required by dependent claim 10, no *prima facie* case of obviousness has been established with respect to claim 10. The rejection of claim 10 under 35 U.S.C. § 103(a) based on *Prince*, *lizuka*, and *Wessels* is therefore improper.

V. Regarding the rejection of claims 11, 12, and 17-19 under 35 U.S.C. § 103(a) as being unpatentable over *Prince*, in view of *lizuka*, and further in view of *Hernandez-Guerra*

Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 11, 12, and 17-19 because a *prima facie* case of obviousness has not been established with respect to the claims.

Claims 11 and 17-19 depend from claim 7 and therefore includes all of the elements recited therein. Claim 12 depends from claim 1 and therefore includes all of the elements recited therein. The Examiner states that *Prince* and *lizuka* are “silent as to the use of an ultrasound-array-based non-invasive diaphragm position and motion tracking for radiation therapy” (Office Action at page 4). However, the Examiner relies on *Hernandez-Guerra* for allegedly teaching this claimed element (Office Action at pages 4-5).

Even assuming this allegation is true, which Applicant does not concede, *Hernandez-Guerra* fails to cure the deficiencies of *Prince* and *lizuka* discussed above. *Hernandez-Guerra* discloses “a signal from a physiological monitor is used to generate a gating signal to gate the radiation beam at the optimal periods” (paragraph 0013).

Hernandez-Guerra does not teach or suggest “detecting the position of the patient’s diaphragm by means of an array of at least two ultrasound transducer

elements on the patient extending in the direction of the longitudinal (z) axis of the patient over the lung sinus, wherein the position of the diaphragm is determined based upon the difference between the signals received by the individual transducer elements,” as recited in claim 1 and required by dependent claim 12. Moreover, *Hernandez-Guerra* does not teach or suggest “an array of at least two ultrasound transducer elements for placing on the patient in the direction of the longitudinal (z) axis of the patient to extend over the lung sinus, wherein the position of the diaphragm may be determined based upon the difference between signals received by the individual transducer elements,” as recited in claim 7 and required by dependent claims 11 and 7-19.

At least because *Prince*, *lizuka*, and *Hernandez-Guerra* fail to teach or suggest each and every element recited in independent claims 1 and 7 and required by dependent claims 11, 12, and 17-19, no *prima facie* case of obviousness has been established with respect to claims 11, 12, and 17-19. The rejection of claims 11, 12, and 17-19 under 35 U.S.C. § 103(a) based on *Prince*, *lizuka*, and *Hernandez-Guerra* is therefore improper.

VI. Regarding the rejection of claims 1, 12, and 13 under 35 U.S.C. § 103(a) as being unpatentable over *Hernandez-Guerra* in view of *Prince*, and further in view of *lizuka*

Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 1, 12, and 13 because a *prima facie* case of obviousness has not been established with respect to the claims.

As established above, neither *Prince* nor *lizuka* teach or suggest the claimed “at least two ultrasound transducer elements on the patient extending in the direction of the

longitudinal (z) axis of the patient over the lung sinus, wherein the position of the diaphragm is determined based upon the difference between the signals received by the individual transducer elements," as recited in claim 1. *Hernandez-Guerra* fails to cure the deficiencies of *Prince* and *Iizuka*. *Hernandez-Guerra* discloses "a signal from a physiological monitor is used to generate a gating signal to gate the radiation beam at the optimal periods" (paragraph 0013). *Hernandez-Guerra* does not teach or suggest "detecting the position of the patient's diaphragm by means of an array of at least two ultrasound transducer elements on the patient extending in the direction of the longitudinal (z) axis of the patient over the lung sinus, wherein the position of the diaphragm is determined based upon the difference between the signals received by the individual transducer elements," as recited in claim 1.

Accordingly, *Hernandez-Guerra*, *Prince*, and *Iizuka* fail to establish a *prima facie* case of obviousness with respect to claim 1, at least since the references fail to teach each and every element of the claim. Claims 12 and 13 depend from claim 1 and are thus also allowable over *Hernandez-Guerra*, *Prince*, and *Iizuka*, for at least the same reasons as claim 1. The rejection of claims 1, 12, and 13 under 35 U.S.C. § 103(a) based on *Hernandez-Guerra*, *Prince*, and *Iizuka* is therefore improper.

VII. Conclusion

In view of the foregoing remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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